COMMISSION
OF THE
EUROPEAN COMMUNITIES

Directorate-General for Agriculture

VI/B/II.2

VI/1526/92-EN-Rev. 4
BAM/kod

THE EU INTERNAL MARKET

- A STRATEGY IN THE FIELD OF ANIMAL AND PLANT HEALTH

October 1994

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I. INTRODUCTION

1. The purpose of this paper is to give an overall view of the strategy the European Union has developed and implemented to prevent the spread of animal diseases and harmful organisms for plants in connection with the abolition of border controls as of 1 January 1993.

Border controls are in place to ensure that animals, plants or their products which are to be imported, satisfy the health standards applicable to that country. With the completion of the Internal Market the rules for production and marketing in the veterinary and phytosanitary field are now the same for all Community production, irrespective of whether the animals, the plants or their products are to be sold within the Member State or go into intra-Community trade, i.e. the standard will be the same.

By their nature, border checks between Member States in the form of documentary checks, identity checks and phytosanitary or veterinary checks are incompatible with the completion of the Internal Market. The complete phasing-out of import checks could only have been realized if they were replaced by a set of alternative measures which in a comprehensive way prevented the introduction or the spread of animal diseases and harmful organisms to plants into areas where they are not established. With the abolition of border controls it was no longer possible nor meaningful to operate on a country-by-country basis in relation to disease control. For the Community with common standards and no border controls there is no difference

- between protecting one country from another country or

- between protecting one part of a country from another part of the country or for that matter the protection of the rest of the Community.

2. The alternative strategy to cater for this new situation is based on transferring the veterinary or phytosanitary check to the point of origin or dispatch for Community production, reinforced checks on imports from third countries at the Community border and the application of the principle of regionalization in disease and harmful organism control. A region is now defined according to its specific health status.

The concept of regionalization has been recognized internationally in the GATT-Agreement on the application of sanitary and phytosanitary measures signed at Marrakesh on 15 April 1994, in Article 6 page 5 and in Annex A, pages 9-10:

'6. Pest- or Disease-Free Area - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease does not occur.

NOTE: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area - whether within part of a country or in a geographic region which includes parts of or all of several countries - in which a specific pest or disease is known to occur but is subject to regional control measures such as the establishment of protection, surveillance and buffer zones which will confine or eradicate the pest or disease in question.' - the text references cited are contained in Annex VI, to this document.

3. In the EU context a distinction should be made between the veterinary situation and the plant health situation.

In the veterinary field regionalization is considered to mean the application of strict controls to a part of the Community to control and eradicate a disease while preventing spread to other

areas, thus permitting free movement of animals and products outside the affected area.

In the plant health field it is necessary to take account of differing pest and disease situations and differing crop and growing conditions within the Community. As a consequence, 'protected zones' exposed to particular plant health risks have been defined and have been accorded special protection. There is provision for two types of such zones, namely zones where particular harmful organisms established elsewhere in the Community are not endemic or established and zones in which there is a danger that certain harmful organisms will establish themselves, given propitious ecological conditions, for particular crops, despite the fact that these organisms are not endemic or established in the Community.

4. In the following the details of the strategy for the veterinary field is described in Part II, whereas the situation for the phytosanitary field is laid out in Part III. The principles of the strategy have been hammered out and confirmed by a number of Council and subsequent Commission Decisions.

II. EU-STRATEGY FOR DISEASE PREVENTION, CONTROL AND ERADICATION FOR ANIMALS AND ANIMAL PRODUCTS

1. The strategy can be summarized in the following principles:

   - The progressive achievement of an overall high health status in the Community through eradication programmes.

   - Non-vaccination against major diseases like Foot-and-Mouth Disease (FMD) and Classical Swine Fever (CSF) (Hog Cholera) combined with total stamping-out policy in case of a disease outbreak. Total stamping out is applied in the case of most OIE list A diseases.

- Reinforcement of veterinary checks at the point of origin and dispatch, combined with re-inforced harmonized and unified checks on animals and animal products entering the Community from third countries.

- Computerized information on the movement of animals within the Community (ANIMO) and computerized information on any irregularities detected through veterinary checks on imports from third countries (SHIFT).

- Common rules and decisions for disease control, including:

  a) a Community system for rapid notification of disease occurence;

  b) harmonised methods for control of exotic diseases;

  c) contingency plans for dealing with epizootics;

  d) Epidemiology Units;

  e) reference laboratories to ensure uniformity of testing etc..

- Application of the regionalization concept

- Competence - role of the Member States and role of the Commission - Standing Veterinary Committee

- Financial support and compensation - veterinary fund to underpin the abovementioned elements

2. In the following these elements will be further developed. A number of annexes are added to provide a complete description of the situation.

   * Annex I gives a summary of the disease status in the Community or parts thereof.

* Annex II contains maps of the EU showing regions subject to restrictions due to specific disease occurrence.

* Annex III contains a scenario for measures to be applied in case of a disease outbreak:

  a) isolated outbreaks,
  b) more widespread and/or numerous outbreaks.

* Annex IV summarizes the rules of compensation in case of outbreaks of some important diseases such as FMD, CSF/Hog Cholera, ASF or CBPP.

* Annex V and VI - Extracts from SPS Agreement.

* Annex VII - Summary of Animal Health import policy in the Single market.

IMPLEMENTATION OF THE EU STRATEGY

3. Achievement of a high health status.

Eradication programmes for Brucellosis, Tuberculosis, Leucosis and, latterly Brucella Melitensis, were introduced at an early stage in the development of EU legislation.

During the '70's and '80's outbreaks of exotic disease occurred regularly in some Member States, e.g Foot-and-Mouth Disease, Hog Cholera, African Swine Fever. These diseases were controlled by the majority of Member States by vaccination, where available.

A cost benefit study on Hog Cholera during the later '70's suggested that eradication would be a more efficient policy. This was followed up by adoption of legislation aimed at eventual eradication of the disease and cessation of vaccination.

A similar approach to Foot-and-Mouth Disease led to the introduction of harmonised control measures, including a total slaughter policy, in January 1987, and final cessation of vaccination in August 1991.

Thus, the Community has moved towards a high health status in respect of all the epizootic diseases. This status has been achieved in respect of most List A diseases (see Annex I).

The remaining pockets of infection have been isolated (see Annex II).

The means of achieving and monitoring this high status are the subject of later paragraphs.

4. The adoption of non-vaccination policies

Non-vaccination policies have been adopted in principle for all List A diseases except Newcastle Disease. Vaccination was finally stopped in April 1988 for Hog Cholera and, in August 1991 for Foot-and-Mouth Disease. For the other exotic diseases vaccination has never been practiced routinely, and is prohibited except in an emergency situation.

Emergency vaccination will be possible, subject to agreement between the Commission and the Member State concerned. This has been done for African Horse Sickness in the Iberian peninsula. However, the fundamental policy is to slaughter and destroy all susceptible animal on the affected holding, and other dangerous contacts, and to implement strict area movement controls.

5. Reinforcement of veterinary checks at the point of origin and dispatch and at entry points with the Community

The absence of checks at internal frontiers makes it imperative that adequate checks are carried out at the origin or point of entry of the animals and products. This principle is achieved by the introduction of several legal instruments.

By this legislation:

a) harmonised and unified rules are applied to products being imported from third countries,

and,

b) the checks on the farm of origin or place of dispatch, in line with current legislation governing the premovement tests and examination to be carried out, are enforced by the Member States of origin, with spot checks being allowed at the destination to ensure compliance with the legislation.

6. Computerised information systems

To facilitate the control of animal movements, the Commission has installed a computer system (ANIMO) which links local offices throughout the EU by computer (about 2,500 workstations).

These enable advance notification of animal movements to be made from origin to destination, thus ensuring that the authorities at the destination are aware of the imminent arrival of animals, and facilitating the carrying out of spot checks. The existing EU health certificates will continue to accompany animals in intra-Community trade.

Linked with this will be the SHIFT system, which is a computer network linking frontier posts, to control imports from third countries.

7. Common rules and decisions for disease control

Certain provisions have been made to facilitate the control of the epizootic diseases when they arise.

a) Notification of disease

All List A diseases are compulsory notifiable in all Member States. This means that they must inform all other Member States and the Commission within 24 hours of the new occurrence of an epizootic disease in a new region, and every week during an epizootic. This is done by direct computer link, or by telex if necessary.

b) Harmonised methods for control of exotic diseases.

Essentially, a total slaughter policy has been adopted, with strict control on infected holdings, and in the infected area. These rules have been defined for Foot-and-Mouth Disease, Classical Swine Fever, Newcastle disease and Avian Influenza and the other exotic diseases.

Routine vaccination remains only for Newcastle Disease.

Legislation is also in place for African Horse Sickness, in which case total slaughter is not mandatory, and vaccine may be used.

c) Contingency plans

Contingency plans must be presented by each Member State for the control of exotic diseases. These plans must be approved by the Commission. They must contain provisions to supply the necessary equipment, facilities and expert staff to deal with an epizootic of a reasonable size. They require that the overall responsibility for the measures rests with the central authority. Regional and local disease control centres must also be established, and their duties are defined.

d) Epidemiology Unit (Commission)

This unit is responsible for epidemiological aspects of the Commission's work. These include:

- Data handling systems, i.e. disease reporting, surveillance, import control information and animal movement control data.

- Risk and Cost Benefit Assessment and Contingency Planning.

- Training programmes - related to emergency disease situations.

In the event of a disease epizootic, the unit will provide data and epidemiological advice to the Commission and the Community Crisis Unit (see p. 14). It will also be responsible for data handling and for providing specialist advice to national epidemiology units. Members (accompanied by specialists from Member States) may visit the infected area in the early stages of the epizootic, to assist in the organisation of national epidemiology teams and in the actual epidemiological analysis on the ground.

e) Reference Laboratories

To date, Community reference laboratories have been established for Foot-and-Mouth Disease diagnosis, Foot-and-Mouth Disease vaccine control and diagnosis of Hog Cholera, African Horse Sickness, Newcastle Disease and Avian Influenza. The objective is to ensure that the most up to date diagnostic methods are used, in a standarised way throughout the EU, and to ensure that Foot-and-Mouth Disease vaccines for emergency use are potent and safe. Routine 'blind' trials are carried out to test the efficiency and repeatability of national laboratories' methods. Reference laboratories for other diseases are under discussion.

8. Application of the regionalisation concept

a) Certain zones have already been delineated within the Community for which restrictions apply in respect of certain diseases, i.e. African Horse Sickness and African Swine Fever. This areas may not send animals or products to other areas of the Community, as appropriate to the disease (Annex II).

b) For new occurrences of disease, the minimum size of protection zones and surveillance or buffer zones is defined in EU law, as well as the minimum rules to eradicate the infection and restrict movement to prevent extension outside the restricted area. These

minimum conditions are imposed automatically by the Member State concerned, but are re-evaluated as soon as possible by the Commission. The actual area is defined on the basis of geographical features, vector studies, meteorological conditions, epidemiological data and administrative boundaries (see Annex III). It may be extended to provide a buffer zone as extra security against spread outside the surveillance zone. The area may also extend into neighbouring Member States if necessary.

c) Restricted areas are policed by the appropriate authorities, under an agreed plan which involves cooperation between the civil police, the veterinary authorities and the industry in the country concerned. These plans are discussed in the Standing Veterinary Committee before adoption. EU missions are undertaken regularly to check on the implementation of the rules applied to the areas concerned.

d) Serological monitoring outside and inside the areas is routinely carried out. Products which could carry infection may not leave the area, either for use within the country or for export to other Member States. In the case of African Horse Sickness and other ???, vector studies are carried out.

e) All Member States have access to laboratory diagnosis facilities, either in their own or in other EU laboratories. Samples from all suspects are examined in these laboratories. The authorised national laboratories for Foot and Mouth Disease, Avian Influenza, Newcastle Disease and Hog Cholera are defined in EU legislation, and will be for the other exotic diseases.

f) In the absence of disease outbreaks, surveillance is maintained through routine investigations of herds and flocks. This is based on :

- reporting of disease by the herd owner. All Member States carry out disease awareness programmes to ensure that the farmers and others in regular contact with livestock are alert to the possibility of OIE List A diseases in particular.

- presence of veterinary practitioners on the farm. The overall ratio of practitioners to herds in the Community is 1 : 338.

- provision of diagnostic laboratories. All Member States have laboratories which receive specimens from farms via practitioners and/or directly from farmers.

- surveillance in the abattoir. Ante- and post-mortem inspections provide an opportunity to detect certain diseases, such as vesicular diseases, CBPP etc.

- herd health programmes. Most Member States have official and voluntary programmes aimed at improving the health of individual herds and flock. These provide surveillance for specified diseases, such as IBR, Leptospira, Maedi/Visna and Mycoplasma spp, and also give an opportunity for a veterinary presence on the farms, which are mainly the top breeders.

- serological surveys. These have been used to assess the prevalence of certain diseases. Furthermore, serosurveillance was done after the Hog Cholera outbreaks, and is continuing in areas where there is a potential for the continuing presence of disease, especially in wild boar. Similarly, serosurveillance is done where needed for Swine Vesicular disease, African Swine Fever and Contagious Bovine Pleuropneumonia. Following Foot-and-Mouth Disease outbreaks, serosurveillance was not previously done, in view of the vaccinal status at the time, but probang surveys were carried out strategically round the affected holdings. Since the cessation of vaccination, serosurveys have been used (Italy '93 and Greece '94).

- epidemiosurveillance on farm by encouraging farms to have contacts with their veterinarians for routine work. Incentives would be given for those participating in the scheme. Such farms would have a defined health status and would maintain it through movement restrictions. The veterinarian would be legally responsible for maintaining standards.

Thus, by concentrating on the actual infected area, it is possible to make the most efficient use of veterinary and administrative resources, to quickly contain and eradicate the disease.

Furthermore, by using a regionalisation policy, it is possible to permit free movement outside the infected area without risk of extention of the disease to other areas of the Community.

9. a) Competence for control measures

The responsibility for the implementation of control measures and import rules rests with the Member States. Each has its own contingency plans, approved by the Commission (in progress). However, the minimum standards are laid down in EU legislation.

The Commission is responsible for ensuring that the measures are fully and properly applied, and for requiring additional measures if necessary. This work is carried out by the Veterinary Inspectorate in close cooperation with the Veterinary and Zootechnical Legislation Unit, and with co-opted experts from Member States if necessary.

The Commission also provides and/or pays for technical assistance to Member States if needed and coordinates between Member States, especially in the case of an epizootic near a border.

b) The Standing Veterinary Committee and the Safeguard Clause

The Standing Veterinary Committee meets twice a month normally, but more frequently if necessary. It is divided into two sections: Animal Health and Public Health. It is comprised of representatives of all Member States. In the context of exotic disease control, the Committee is required to give its opinion on proposals from the Commission, made usually unter the 'safeguard clause'. Under this provision, Member States are required to inform other Member States and the Commission of the appearance of any new disease situation. The Commission is required to study this situation, in cooperation with the Member State(s) concerned, and give an opinion on the

national measures which have been implemented. These measures are based on the minimum standards laid down in the EU control legislation, but also take into account special geographical, meteorological and epidemiological features. If the Commission considers that the measures taken by the national authorities are not adequate, it may demand additional safeguards immediately. These safeguards must then be referred to the Standing Committee, for formal adoption.

c) Community Crisis Unit

As soon as it becomes apparent that there is a new disease epizootic, a Crisis Unit may be established. This group will be comprised of experts in the disease, as well as senior veterinary administrators, and Commission staff. It will liase with the Commission epidemiology unit. It will meet normally in the Commission offices. Its role is to oversee the evolution of the epizootic, and advise the Commission on additional measures to be taken to prevent extention of the disease to other areas. It may also meet 'on-site' if necessary. It will play a special coordinating role in the event of an epizootic near a Community border. This Unit is, in effect, a sub group of the Standing Veterinary Committee.

10. Financial support and compensation

Council Decision 90/424/EEU established a fund for veterinary expenditure. This make a Community financial provision for many areas of veterinary competence, e.g.:

- payment of compensation for slaughtered animals, up to 70% of Member States costs;

- establishment of vaccination campaigns in adjacent third countries;

- establishment of antigen/vaccine banks;

- training in disease control work;

- reference laboratories;

- strengthening of veterinary infrastructures;

- research towards development of new legislation.

Thus, the whole strategy is underpinned by making suitable financial provisions from the Community budget.

CONCLUSION

In the absence of frontier controls, the strategy for the eradication of disease and the prevention of spread must concentrate on the actual source of infection. This infers a regionalisation policy for dealing with epizootic diseases. This policy has been used already, and shown to work, e.g. in Germany 1987/88, and Italy in 1989 and 1993, when Foot and Mouth Disease was contained by measures introduced by the national authorities under consultation with the Commission.

Classical Swine Fever was eliminated from Belgium using a regionalisation policy, without extention of disease to other parts of the Community.

In the Iberian Peninsula, African Swine Fever has been steadily eradicated from a previously large infected area, and the rest of the country maintained free from disease, by measures first introduced nationally, then agreed at Community level. Also in the Iberian Peninsula, since 1990, the measures introduced for African Horse Sickness under Community control have proven their effectiveness for eradication and have permitted free movements between the unaffected area of Spain and the rest of the Community.

Regionalisation has been shown to work in the EU. Further safeguards now being applied, such as the establishment of epidemiology units and national contingency plans, together with EU financial assistance should help ensure the continuing success of this approach.

III. EU STRATEGY FOR THE PREVENTION, CONTROL AND ERADICATION OF PLANT PESTS AND DISEASES:

1. Generalities

The abolition of frontier controls within the European Community on 1.1.1993 had serious implications on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community. In effect, barriers related to internal frontiers could no longer be a tool to confine pests and diseases, and a new approach towards the prevention of their spread became necessary.

The Community therefore set up a "new strategy in the field of plant health". This was negotiated and transposed into Community legislation which came into force on 1 July 1993: under this new plant health regime the emphasis has shifted to controls at the origin, i.e. on the grower's premises. Plants which do not meet the necessary health requirements may not move within or between Member States. The former phytosanitary certificate has been replaced by a "plant passport" for all those plants and plant products originated and moving within the Community for which a plant health risk is identified. Whilst plant health import controls are done at the external borders of the Community, with the system of phytosanitary certification for imports from third countries continuing as before, this being the established system for international trade under the International Plant Protection Convention. Thus it should be noted that there is a distinction between the system set up for Community production, and that in respect of third country production;

This new strategy has necessitated the introduction of Community legislation providing for:

a) the extension of the Community plant health regime to movements of products also within individual Member States;

b) harmonised methods for phytosanitary checks of harmful organisms in the Community at the point of origin;

c) registration system of producers and importers;

d) restructuring and adjustments of the lists of organisms harmful to plants and plant products, based on scientific and technical evidence and standardisation of testing methods;

e) a plant passport system;

f) implementation of the "protected zones" concept;

g) a Community system for managing and monitoring measures to protect the Community as a whole, including movements of plants and plant products within the Community;

h) training for EU and national inspectors, and the establishment of an EU plant health inspectorate;

i) a system of Community financing of control measures, including eradication of harmful organisms, linked with a system of financial liability of Member States under certain circumstances.

j) import checks on third country products at the point of entry to prevent the introduction of foreign harmful organisms;

k) a Community system for rapid notification of harmful organisms: interception/occurrence/appearance;

2. Detail

COMMUNITY PRODUCTION

The new plant health regime has necessitated the putting into place of a complex of alternative measures to replace the previous import checks at the borders of individual Member States. The measures have the objective of defending the common interest in preventing the introduction or the spread of harmful organisms to plants or plant products in areas where they are not established and where they would present a risk to plants planted or otherwise growing there. Key aspects of the regime are as follows: -

a) Extension of the scope of the Community plant health regime to domestic trade

From the above mentioned objective, it can be deduced that it does not make any difference for the Community whether a specific area must be protected against harmful organisms from another country,

or against harmful organisms from another part of the same country. Consequently, domestic production, as well as the production of other Member States, must be subjected to the same plant health regime.

b) Plant health controls to be carried out at the place of production

With the abolition of import checks, all Member States had to be in a position where they could have confidence in measures taken by other Member States: in the past import checks were often performed because the consignee countries were not always convinced that the plant health controls in the forwarding countries had been done properly.

In order to meet this objective, the new plant health regime prescribes the plant health checks to be done at the most appropriate place, i.e. at the place of production, and at the most appropriate times, i.e. during the growing season and immediately after harvest.

c) Registration of producers and importers

Any producer subject to such checks, must be listed in an official register. To this end producers must submit an application, through an appropriate registration procedure, to the responsible official bodies of the relevant Member State.

A similar procedure is applicable to importers of certain plants and plant products. On receipt of an application the responsible official bodies must first establish that the producer and importer are able and willing to meet certain uniform obligations, and once this is confirmed must list them in an official register under a registration number by which it is possible to identify them.

The obligations to which the producers and importers are subject can be summarized as follows:

i) to keep an updated plan of the premises on which plants, plant products or other objects are grown, produced, stored, kept or used by the producer or importer, or are otherwise present;

ii) to keep records, with a view to having complete information available for the responsible official bodies, on plants, plant products or other objects,
-purchased for storage or planting on the premises,
-under production, or
-dispatched to others,
and to keep related documents for at least one year;

iii to be available personally or to designate another person technically experienced in plant production and related plant health matters, to liaise with the responsible official bodies;

iv) to carry out visual observations as necessary and at appropriate times, and in a manner laid down in guideline instructions given by the responsible official bodies;

v) to ensure access for persons entitled to act for the responsible official bodies, in particular for inspection and/or sampling, and to the records referred to in point ii) and related documents;

vi) to otherwise cooperate with the responsible official bodies.

Additional obligations of a general nature may be set up by Member States to facilitate the assessment of the plant health situation on the premises; they have to be within the limits of national law and may take into account the details of the production and, where appropriate, import conditions, in particular the type of crop, the location, the size, the management, the staffing and the equipment. There is provision for the exemption from official registration of small producers trading solely in the local market to non-professionals, ("local movement").

d) Establishment of common plant health standards for domestic and intra EC-trade

The standards for Community production are restricted to "Community quarantine organisms". These are harmful organisms which are known to occur in certain parts of the Community, but are not endemic or established throughout the Community.

The standards therefore do not concern "quality organisms", which reduce the usefulness of infected plants or plant products. The standards mainly apply to material intended for planting, and other selected material including wood and material for consumption of particular plant health concern, such as potatoes.

e) The use of plant passports

In international trade the use of a phytosanitary certificate is the established instrument to prove that a given consignment has successfully passed the required plant health checks.

However, this system of issuing certificates is not compatible with the concept of the Internal Market, because the layout and format does not give sufficient guarantees of the identity of a single product in a given consignment. Moreover, it is a document issued by the official plant protection service of the exporting country and addressed to the official plant protection service of the importing country, and thus not adapted to the domestic trade. Finally, the said certificates are not adapted to the new concept of "Protected zones".

A new system of plant passports forms the new regime. These plant passports consist of an official label and an accompanying document which give evidence that the material has successfully undergone the Community checking system. During a first phase a system making use of a simplified plant passport with certain standardization being used. Later on a standardized lay-out for different types of plants or plant products is envisaged.

The plant passport should include the following details:

1. 'EEC-plant passport'
2. indication of EC Member State code
3. indication of the responsible official body or its distinguishing code
4. registration number of producer or importer
5. individual serial, week or batch number
6. botanical name
7. quantity

8. where appropriate, an indication with the distinctive marking "ZP" that the material can enter a specified protected zone and, if so, which one
9. in the case of replacement of a plant passport, a distinctive marking "RP" and code for the originally registered producer or importer
10. where appropriate, an indication of the country of origin or consignor country for third country products.

The details of items 1-5 above as a minimum must be recorded on the official label part of the plant passport, and this label must be attached either to the products or to their packaging or to the vehicles transporting them. The accompanying document with any remaining information can be any document which is normally used for trade purposes.

The plant passports must be produced, printed and/or subsequently stored either by the responsible official bodies or - under their control - by the producer or importer.

For the issuing of the plant passports, i.e. the establishing, in particular the filling in of the information, and the actions necessary to make them available for use by the applicant, a specific procedure has to be followed under the control of the responsible official bodies.

A plant passport may be replaced if the status of the material or the composition of the consignment changes. The replacement passport is identified by the code "RP" and can only be prepared by the responsible official body concerned.

The plants and plant products covered by the new system of plant passports include, at the risk of over-simplification:

- plant propagating and production material (cuttings, rootstocks, seedlings and young plants for growing on,bulbs, corms and tubers, etc.)
- seed potatoes
- fruits of Citrus clementina retaining peduncles and leaves
- wood of some broad leaved genera and conifers.

A range of lighter controls, called trace-back, has been set up for plants posing a lower plant health risk. Producers of such material still need to be registered, but are not subject to the plant passport system. Material covered by this system includes ware potatoes and citrus fruit. Also certain types of planting material (detailed in Annex VA to Directive 77/93/EEC) prepared and ready for sale to the final consumer and whose production is clearly separate from that of other material, are not subject to the plant passport system although again producers of such material do have to be registered.

f) "Protected Zones" (ZPs) (see para 3 for definition)

The new strategy accepts that special arrangements are necessary to take account of differing pest and disease situations and differing crop and growing conditions within the Community. As a consequence, "Protected Zones" exposed to particular plant health risks have been defined and have been accorded special protection. The borders of each zone and the type of special protection have been specified for each case, taking into account the specific biological interaction of host plant-harmful organisms concerned, see Annex II.

This regionalisation-concept avoids the possibility of criticism by third countries of "fortress" Europe; moreover, it will not disrupt actual intra-Community trade.

g) Checks during marketing

To ensure compliance with the Community plant health regime, a system of official checks during marketing is necessary. These checks normally shall be only occasional and at random, not targeted, and not carried out specifically at national boundaries.

h) Establishment of a plant health inspectorate

In order to increase mutual trust between the Member States and to verify the correct and uniform application of the new plant health regime at Community level, checks and inspections may be organized under the authority of the Commission by Community experts.

These experts now monitor examinations and inspections carried out by Member States and, in conjunction with the official services of the Member States, they can conduct, plant health checks on plants and plant products coming from non-member countries.

Further, they undertake inquiries and investigations regarding applications from the Member States for derogations in respect of certain requirements, they monitor the surveys done by the Member States in order to define their Protected Zones and carry out on-site investigations regarding protective measures ("safeguard clauses") adopted or applied for by the Member States (see para 6below). They will eventually carry out activities specified in technical protocols and agreed with non-member countries.

i) Establishment of a system of Community financial "solidarity" and Member States' "liability"

As the new plant health regime may represent certain risks for the Community or parts thereof, it is fair that the Member States should not be left alone to face the possible dangers.

The Commission has consequently proposed a system of financial "solidarity", to contribute towards public expenditure incurred by a Member State in taking specific measures to control or eradicate new outbreaks of quarantine organisms. However, such financial expenditure should be reimbursed by a second Member State, if it is established that the relevant outbreak is the result of negligent inspections made under the responsibility of that second Member State.

The latter is called Member States' liability, and should encourage a correct application of Community rules, thus contributing to the establishment of mutual confidence between Member States, a necessary adjunct to the abolition of all plant health import checks.

THIRD COUNTRY PRODUCTION

The plant health regime applicable to imports from third countries has not changed drastically. The standards have remained the same, and the system of phytosanitary certificates also continues to apply, because this is the established system for international trade under the International Plant Protection Convention.

j) Compliance with the requirements of the plant health directive are checked, on behalf of the Community, on the occasion of the first introduction of the plants or plant products. In case of satisfactory checks the products are subsequently assimilated to Community production. By this process products obtain a plant passport if the equivalent products of Community origin are required to have a plant passport (viz. those products listed in Annex V part A to Council Directive 77/93/EEC); otherwise the products are free to be moved within the Community without phytosanitary documents. With regard to the checking on first introduction into the Community, it should be noted that technical arrangements between the Community and certain third countries may be made with a view to transferring physical import checks from the external border of the Community to the third country producing the material. In such cases, the checking at the border of the Community could be restricted to documentary and identity checks and only occasional physical checks.

3. Legal basis

STET Directive 77/93/EEC as last amended by Council Directive 94/13/EEC.

4. Competence for phytosanitary measures

The responsibility for the implementation of measures laid down in Community law rests with the Member States. Each Member State designates one single and central coordination and contact authority (in most cases the national official Plant Protection Organization).

The Commission is responsible for monitoring uniform and correct implementation of Community law, through a Community inspection system.

5. The Standing Committee on Plant Health

The "Standing Committee on Plant Health" composed of representatives of all Member States and chaired by a representative of the Commission meets regularly, i.e. normally each month, but more frequently if necessary. The Committee is charged to examine and to give an opinion on draft measures to be adopted by the Commission and to discuss any matter related to plant health.

6. "Safeguard clause" and notification of detection of harmful organisms:

Member States must take measures to prevent the dissemination of, or to eradicate, any pest or disease which has been unknown, either in the entire Community, or in a protected zone. The detection must be notified to the Commission and a Community risk assessment takes place.

Under the provisions of the safeguard clause (Article 15(3) of Directive 77/93/EEU), the Commission may adopt any measure necessary to eliminate, reduce or confine the risk, based on the opinion given by the aforesaid Standing Committee. The nature of these measures may be very variable, pending on the risk assessment in respect of the specific hostplant-organism interaction concerned.

Where necessary, harmonised rules binding all Member States will be adopted. If the Commission considers that the measures taken by Member States are not adequate, it may require additional safeguards immediately.

In addition an EU network for real time notification of new occurrences of these harmful organisms both on import interceptions and Community inspections is being established. (Point k).

ANNEX I

All Member States can be considered as free from the following List A disease:

* Capripox
* Rinderpest
* Peste des petis ruminants
* Vesicular stomatitis
* Bluetongue (and EHD)
* Lumpy skin disease
* Rift valley fever
* Teschen disease
* African Horse sickness
* Fowl Plague

Other List A diseases exist, or have existed recently, in some parts of the Community, i.e.:

* Foot and Mouth Disease (Italy 1993, Greece 1994)
* African Swine Fever (Saidla, west Spain and Sardinia)
* Hog Cholera (localised parts of Germany, Italy)
* CBPP (Portugal and isolated cases in Spain and Italy)
* Swine Vesicular Disease (Italy)
* Newcastle Disease - Velogenic Visceral strains of virus are normally absent. (All Member States except Denmark and Ireland use vaccine in commercial poultry).

ANNEX II

Areas with restrictions due to African Swine fever

October 1994

ANNEX II

Area under restrictions for foot and mouth disease

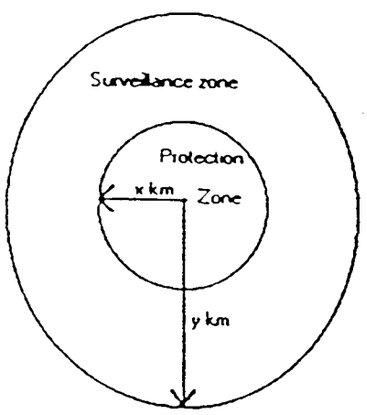
Also some holdings with buffalo in Caserta Italy

October 1994

Annex IIIa

Area restrictions to be applied in the case of appearance of an epizootic disease

Scenario one: Control by measures defined in the basic Directive, in the case of a limited epizootic



The competent authority must, when establishing these zones, take account of:

-the epidemiological evidence
-geographical features
-trade patterns
-administrative boundaries.

The minimum values for x and y for diseases such as FMD and Hog Cholera are 3 and 10km respectively. For vector borne diseases such as AHS, these values are 100 and 150km.

Minimum restrictions are

Protection zone
-census and veterinary inspection of all holdings
-prohibition on movement and transport of animals except for emergency slaughter under license
-controls of vehicle movements
-restrictions on milk, meat, semen, manure etc as appropriate
-prohibitions of animal gatherings

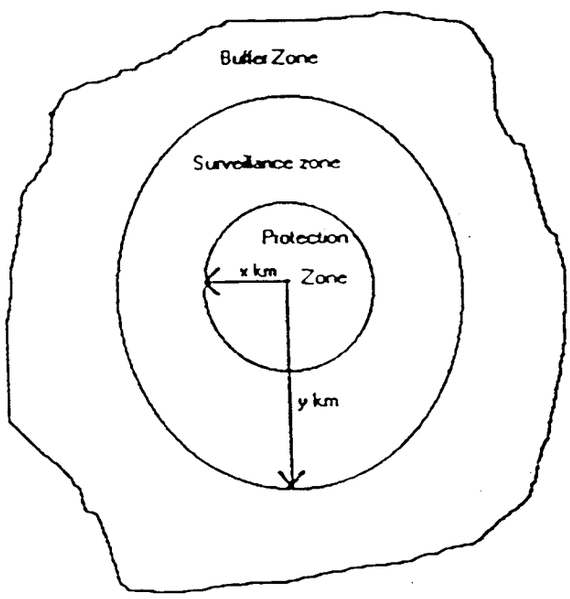
Surveillance zone
-census of all holdings
-transport of animals within the zone only initially, then to abattoir only for emergency slaughter
-movement of animals prohibited except for pasture
-all movements subject to authorisation
-controls of vehicle movements
-restrictions on breeding movements
-prohibitions of animal gatherings

The restrictions must be maintained for at least 15 days after slaughter, cleansing and disinfection in the last outbreak in the protection zone. After that, the rules for the surveillance zone apply to the whole area for at least a further 15 days. In the case of AHS, the measures will be maintained for 2 years.

Annex III b

Area restrictions to be applied in the case of appearance of an epizootic disease

Scenario two: Control measures to be extended under the safeguard clause



The protection zone and surveillance zones are extended beyond those required by the basic Directives, according to the local condition. Dimensions x and y could be considerably more than the minimum shown in scenario one.

The minimum restrictions described in scenario one are applied. In addition a Buffer zone is established, taking into account geographical, epidemiological and meteorological factors, in which veterinary inspections are maintained but at a reduced level, and animal movements are limited, in order to provide a margin of safety between the affected areas and the free zone.
An emergency vaccination zone could also be declared. This would be decided on a case by case basis. Vaccinated animals and meat from them would be restricted for a long period after vaccination (up to 2 years).

The measures will be lifted after a minimum of 30 days after final cleansing and disinfection of the last infected holding, assuming vaccine is not used. The actual period will depend on clinical assessment on holdings in the area, and, for some diseases (ie those with less clear symptoms, such as Hog Cholera), a serological survey. The minimum period in the case of AHS is 2 years.

ANNEX IV

Summary of rules of compensation in cases of an outbreak of exotic disease.

Member States can obtain a financial contribution from the Community for the eradication of disease, provided that they have fulfilled the provisions of the relevant control Directive, especially relating to total slaughter and destruction of affected or contact animals, destruction of contaminated feed, eggs, equipment, etc and to the correct establishment and management of protection zones. This contribution relates to compensation to owners for the slaughter of an animals, destruction of milk, cleansing and disinfection and destruction of contaminated materials.

Exceptionally, for Foot-and-Mouth Disease, losses incurred because of prolonged restrictions on marketing of livestock because of an emergency vaccination campaign may also be compensated.

The cost of transporting carcasses to a rendering plant and other eradication measures may also be compensated.

The level of compensation is normally up to 50% of Member State costs. This figure is set at 70% until 1995, then at 60% thereafter, for Foot-and-Mouth Disease.

The rate of compensation may be increased in the case of a prolonged outbreak.

Annex V

Article 9

Technical Assistance

1. Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, *inter alia*, in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.

2. Where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.

Article 10

Special and Differential Treatment

1. In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.

2. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.

3. With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs.

4. Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations.

Article 11

Consultations and Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement, except as otherwise specifically provided herein.

2. In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.

3. Nothing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement.

Article 12

Administration

1. A Committee on Sanitary and Phytosanitary Measures is hereby established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives, in particular with respect to harmonization. The Committee shall reach its decisions by consensus.

2. The Committee shall encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary or phytosanitary issues. The Committee shall encourage the use of international standards, guidelines or recommendations by all Members and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination and integration between international and national systems and approaches for approving the use of food additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs.

3. The Committee shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention, with the objective of securing the best available scientific and technical advice for the administration of this Agreement and in order to ensure that unnecessary duplication of effort is avoided.

4. The Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefor, and, in particular, whether it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B.

SPS Agreement.

Annex II

8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

Article 6

Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence

1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area - whether all of a country, part of a country, or all or parts of several countries - from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, *inter alia*, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.

2. Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.

3. Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

Article 7

Transparency

Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

Article 8

Control, Inspection and Approval Procedures

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

ANNEX VII

EC ANIMAL HEALTH IMPORT POLICY IN THE SINGLE MARKET

DEFINITIONS

1. For the purposes of this document, the following definitions shall apply:

   * **Trade:** means movements between Member States of the EC
   * **Import and Export:** means movements from and to third countries.
   * **Frontiers:** means external borders of the Community.
   * **Internal borders:** means borders between Member States.

COMPETENCE

2. The competence for the setting of rules with the objective of managing the Common Agricultural Policy and the achievement of the Single Market is given to the Council of Ministers, acting on proposals from the Commission, by the Treaty of Rome, Articles 43 and 100a respectively.

3. In the field of animal health rules for imports from non-Member States, the Council has adopted the following Directives and Decisions:

   72/462/EEC concerning imports of live animals (cattle, sheep, pigs and goats), fresh meat and meat products,

   90/426/EEC on animal health conditions on movement and imports from third countries of horses,

   90/675/EEC on veterinary checks on products entering the EC,

   91/67/EEC on aquaculture animals and products,

   91/496/EEC on veterinary checks on live animals entering the EC,

92/438/EEC on computerization of veterinary import procedures (SHIFT Project),

88/407/EEC concerning trade in and imports of bovine semen,

89/556/EEC concerning trade in and imports of bovine embryos,

90/429/EEC concerning trade in and imports of porcine semen,

90/539/EEC concerning trade in poultry and hatching eggs,

91/494/EEC concerning trade in and imports of poultry meat,

92/45/EEC concerning marketing and imports from third countries of wild game meat,

92/65/EEC concerning trade in and imports of animals, semen and embryos not covered in specific Community rules.

92/118/EEC concerning products not covered by specific Community rules.

4. Under the provisions of the Directives, the Commission is required to draw up appropriate legislation, as follows:

Lists of third countries from which imports of various products and animals may take place.

Animal Health conditions and veterinary certificates for imports from individual countries.

Residue plans or guarantees for meat and meat products and live animals.

List of establishments in authorised countries from which imports may take place.

5. These measures are introduced by Commission Decisions, after an opinion from the Standing Veterinary Committee. The proposals from the Commission are based on the results of on-the-spot inspections of the countries concerned, carried out by the Commission's Office of Veterinary and Phytosanitary Inspection, and take account of the animal health situation, particularly the absence of diseases on OIE List A, the means of controlling and eradicating diseases and the veterinary infrastructure in the country concerned.

6. The responsibility for the implementation of all policies, including import controls, lies with the Member States. The Commission Office of Veterinary and Phytosanitary Inspection carries out checks to ensure compliance with EC rules by Member States. Additionally, Member State's own legislation to implement EC law must be submitted to the Commission to ensure that it complies with the EC rules.

DISEASE POLICY

7. Specific policies have been developed generally for the List A diseases. These are detailed in Directives (eg 72/462/EEC for bovine, ovine, caprine and porcine animals and their meat and products). The detailed rules are laid down in individual Commission Decisions for each third country. There are some differences in detail, but some general rules can be stated.

8. Foot and mouth disease.

a) Live animals

Live animals are not imported from countries where FMD has existed, or where vaccination has been carried out, during the previous 12 months, except through a system of isolation and testing in the country of origin and quarantine and testing in the Member State of origin. Vaccinated animals are not imported (or traded between Member States).

b) Fresh meat

Fresh meat is imported from certain countries where FMD occurs. These countries must be on the list (para 3 above). The meat must be from carcases which have been matured at above 2°C for at least 24 hours after slaughter, and the bones and lymphatic glands must be removed. The pH must be checked and found to be below 6.

c) Offal

Offal may only be imported under veterinary control. Certain types of offal may be imported for special uses, but must be processed in the Member State of destination by an authorised method. This is under review.

d) Raw materials for the production of pharmaceutical products (glands, organs, blood).

These may be imported under strict conditions of veterinary supervision and processing in authorised establishments. Importation is "canalised" to ensure delivery to the authorised establishment.

9. Classical Swine Fever (CSF)

a) Live animals

Live pigs are not imported from countries where CSF has existed, or where vaccination has been carried out, during the previous 12 months.

b) Fresh pigmeat or meat products which have not been adequately treated are not imported from countries as under a).

10. Other List A diseases

Policy is similar to CSF (see Directive 72/462/EEC). Some other diseases which are not on list A are included eg Infectious Haematopoetic Necrosis.

11. Other products

Other products, such as semen, embryos, etc are dealt with on a country by country basis. In general terms, imports are not allowed from regions or countries where List A diseases appropriate to the species are present.

12. Regionalisation

This policy has been used in the past, for several countries, whether or not they are Member States, if it is possible to define a free area and to maintain it under satisfactory veterinary control. Conversely, it may be possible to define an infected area and import from that part of the country outside the infected area.

EFFECT OF THE SINGLE MARKET

13. Since the objective of the Single Market is a high health status, EC policy is evolving towards this aim. This has meant some changes in the rules. For example,a non-vaccination policy for exotic diseases has been adopted as part of this objective, and this had meant the introduction of other rules to take account of this new policy.

However, the abolition of internal border checks for the Single Market itself will not affect EC Animal Health rules for imports from third countries specifically. However, reinforced frontier checks are necessary, with the objective of ensuring that products which enter at one port will be fit to circulate throughout the Community, to any Member State.

14. Frontier checks have been agreed for harmonised animals and products. The full import procedure must be carried out at the point of entry for all animals and products currently subject to harmonised EC legislation. This includes a documentary and identification check and a clinical examination.

For non-harmonised animals and products, the checks may be carried out at the point of entry into the Community or at the destination, depending on whether or not there is an appropriate agreement between

the Member States concerned. However, all animals and products will be harmonised by 1/1/94.

The certificate to be issued by the veterinarian at the border crossing has been defined (Decision 92/527/EEC for animals and 93/13/EEC for products). A provisional list of authorised frontier inspection posts has been published.

LIST OF IMPLEMENTING DECISIONS IN RELATION TO IMPORT CONTROLS

79/542/EEC List of approved third countries

92/399/EEC Transitional measures for the new system of veterinary checks on products under 90/675/EEC.

92/424/EEC Detailed rules for identity checks on animals from third countries.

92/430/EEC List of border inspection posts for products.

92/431/EEC List of border inspection posts for animals.

92/432/EEC derogation from individual clinical examination.

92/525/EEC approval requirements for border inspection posts.

92/527/EEC border crossing certificate for live animals.

92/571/EEC Transitional measures for checks on non-harmonised products.

93/13/EEC procedures for veterinary checks at border inspection posts on products from third countries.

93/14/EEC requirements for the veterinary control of products from third countries in free zones or warehouses and customs warehouses.

93/79/EEC transitional measures for live animals.

93/321/EEC reduction of physical checks for horses.

93/ZZZ/EEC Frequency of sampling at frontiers -live animals.